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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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December 23, 2015

The Honorable Nicole Lurie, M.D., M.P.H.
Assistant Secretary for
Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Lurie,

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining the adequacy of the stockpile of pre-pandemic vaccines.

The national vaccine goals for pandemic influenza preparedness call for pre-pandemic vaccine stockpiles to protect 20 million people as well as for manufacturing infrastructure to support rapid production of 600 million doses. At a recent National Academies of Sciences workshop, one industry official noted the dynamic nature of the influenza threat and questioned the match of vaccine stockpiles that were purchased 10 years ago against today's circulating strains.[1] For example, the H5N1influenza emerging in Egypt in 2015 is not necessarily the H5N1 strain that emerged in Vietnam in 2004.

During the November 19, 2015 hearing before the Subcommittee on Oversight and Investigations, Dr. Robin Robinson, the Director of the Biological Advanced Research and Development Authority (BARDA) told the Subcommittee on Oversight and Investigations that BARDA is currently testing stockpiled pandemic influenza vaccines. We would be interested in the test results to determine whether the vaccines would provide protection against the circulating avian flu viruses which devastated U.S. poultry this year. These results would be helpful to the committee in understanding whether the vaccines are protective. At a June 2015 meeting of the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), a CDC official said tests showed that neither H5N8 nor N5N2 viruses cross-reacted with an H5N1 vaccine, suggesting that the vaccine would not be protective.

[1] The National Academies of Science, Rapid Medical Countermeasure Response to Infectious Diseases: Enabling Sustainable Capabilities Through Ongoing Public- and Private-Sector Partnerships, Workshop Summary (2015).

[2] In an interview, Dr. Robinson stated that BARDA's stockpile contained some doses based on a strain called Anhui that is more closely related to H5N8 and H5N2, and that the CDC planned to test whether the Anhui-based H5N1 vaccine would offer any protection against the other avian strains.[3]

There is a need to ensure that the pre-pandemic vaccine stockpile is protective. Earlier this year, the World Health Organization stated the unprecedented number of currently circulating new avian and swine influenza strains is "ominous." Two new highly pathogenic strains of avian flu (H5N8, H5N2) are circulating in the U.S., and they have already caused the death of nearly 50 million birds at a cost of $1 billion to our economy. A health alert issued by CDC on June 2, 2015 notified public health workers and clinicians of the potential for human infection with these viruses, and made recommendations for patient investigation, testing and infection control. If these strains were to make the jump to humans, pandemic risk would increase. These developments heighten our interest in assuring the United States is sufficiently prepared for pandemic influenza.

Innovation, stockpiling and building infrastructure capacity for a rapid medical counter measure (MCM) response to pandemic influenza threats is managed primarily by BARDA programs. From 2005 to 2013, pandemic flu preparedness was funded through a $5.6 billion emergency advanced appropriation, averaging $750 million per year. Funding has shifted to annual appropriations at significantly lower amounts and BARDA's pandemic flu program only received $72 million in Fiscal Year 2015. As a result, HHS has raised an issue of whether BARDA can continue to support the efforts required to prepare for the next pandemic. The FY16 HHS budget request said the following: "This FY 2015 reduction below the request level impedes HHS' ability to maintain existing programs for pre-pandemic influenza vaccine stockpiling and development of influenza antiviral drugs and immunotherapeutics, which are central programs to address critical vulnerabilities for U.S. pandemic preparedness."

While vaccines for seasonal influenza change year-to-year, BARDA maintains a stockpile of roughly $1.75 billion worth of pandemic influenza vaccine. This year, however, BARDA has only budgeted about $20 million – or 1 percent of the stockpile value – for replenishment and maintenance of this asset.

To assist the committee's oversight, please respond to the following questions by January 12, 2016:

1. What are the results of testing BARDA has done on stockpiled pandemic vaccines? Please provide the committee with a list of the tests and the most recent data collected from these tests. How does BARDA evaluate these results in the context of the periodic risk assessments conducted by the HHS Influenza Risk Management Working Group or other HHS experts?

[2] Robert Roos, "BARDA: Recent 'universal' flu vaccine proposals fell short," CIDRAP News (July 23, 2015).
[3] Id.

2. BARDA's testimony discussed BARDA's plans to also test these stockpiles for potency. What were the results of these tests? Were any additional tests conducted to determine if the vaccines in the stockpile are well-matched to the current threats?

3. In your July 31, 2015 letter to the committee, you wrote that "[a]s a direct outcome of the IRAT (Influenza Risk Assessment Tool) process, the agencies [ASPR/BARDA and CDC] are conducting multiple scientific studies to determine whether previously stockpiled H5N1 vaccines confer immunity against HPAI [Highly Pathogenic Avian Influenza] H5 viruses in humans." Are any of the studies completed? If so, what were the findings? If not, when are the studies expected to be completed?

4. What is the status of efforts by HHS agencies and vaccine manufacturers to develop, manufacture, and test new vaccine candidates to H5N2 and/or H5N8 viruses using egg- and cell-based influenza vaccine platforms to supplement existing stockpiled vaccines?

5. Are there any studies that show the effects of long-term storage on the potency of influenza vaccines? If yes, what do the studies show? If not, what is the basis for our understanding about the potency of influenza vaccines? At what point, would the vaccines start to lose potency?

6. What kind of testing of the pre-pandemic stockpile is needed on an ongoing basis and what funding is needed to support this kind of testing?

7. At the CDC's ACIP meeting in June 2015, a CDC official showed data indicating that the stockpiled vaccines do not protect against the current circulating avian strains, and may be distantly related to the viruses. How many doses of vaccine are in the BARDA stockpile contain the Anhui strain that is more closely related to the currently circulating avian strains? Has there been any testing of the vaccines with the Anhui strains on how well they protect against the currently circulating avian strains?

8. What assumptions is BARDA using to determine if/how well the current pre-pandemic stockpiles will protect the public in the event of a pandemic?

9. How do issues like the age of the stockpile and possible mismatch against currently circulating pandemic strains affect these determinations?

10. Are pandemic influenza risk assessments provided to key stakeholders?

11. Given that existing contingency pandemic influenza vaccine stockpiles are aging – most are 5-10 years old – what resources does BARDA need on an annual basis to update the stockpile and prepare for the next pandemic threat?

12. If a rapid MCM response was required to address a seasonal influenza epidemic due to a mismatched vaccine, does BARDA have resources to respond? If so, how? Are resources available to support availability of a matched vaccine?

13. How does BARDA plan to maintain and replenish the stockpile of influenza vaccines, some of which are now a decade old? What funds are planned to be used?

14. Are current stockpiles consistent with the national Strategy for Pandemic Influenza which states the U.S. should have "sufficient vaccine to vaccinate the entire U.S. population within six months of the emergence of a virus with pandemic potential"?

15. What level of annual funding would be sufficient, going forward, to maintain and replenish the stockpile, in order to ensure U.S. preparedness against pandemic influenza? Please detail how these funds would be spent.

If you have any questions, please contact Alan Slobodin of the majority committee staff at (202) 225-2927 or Una Lee with the minority staff at (202) 225-3641.

Sincerely,

Fred Upton
Chairman

Frank Pallone Jr.
Ranking Member

Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Chairman
Subcommittee on Oversight
and Investigations

Attachment